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UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER OF PATENTS AND TRADEMARKS P.O. Box 1450 Alexandria, Virginia 22313-1450

NOTICE OF ALLOWANCE AND FEE(S) DUE

23492

7590

05/07/2003

STEVEN F. WEINSTOCK ABBOTT LABORATORIES 100 ABBOTT PARK ROAD DEPT. 377/AP6A ABBOTT PARK, IL 60064-6008 EXAMINER

HESS, DANIEL A

ART UNIT CLASS-SUBCLASS

2876 356-039000

DATE MAILED: 05/07/2003

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/874 493	06/05/2001	Ronny van't Oever	6811.US.O1	6161

TITLE OF INVENTION: OPTICAL METHOD AND APPARATUS FOR RED BLOOD CELL DIFFERENTIATION ON A CELL-BY-CELL BASIS, AND SIMULTANEOUS ANALYSIS OF WHITE BLOOD CELL DIFFERENTIATION

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO ,	\$1300	\$300	\$1600	08/07/2003

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. <u>PROSECUTION ON THE MERITS IS CLOSED.</u> THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above

B. If the status is changed, pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above and notify the United States Patent and Trademark Office of the change in status, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check the box below and enclose the PUBLICATION FEE and 1/2 the ISSUE FEE shown above.

Applicant claims SMALL ENTITY status.
 See 37 CFR 1.27.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Box ISSUE FEE Commissioner for Patents

Alexandria, Virginia 22313-1450 <u>Fax</u> (703)746-4000

appropriate All further cor	respondence including the below or directed otherwise	Patent, advance orders	and notification	of maintenance fees	quired). Blocks I through 4 s s will be mailed to the current ss; and/or (b) indicating a sepa	i correspondence address as
23492 7:	TE ADDRESS (Note: Legibly mark-ti 590 05/07/2003	p with any corrections or use B	llock 1)	Fee(s) Transmitta	of mailing can only be used for al. This certificate cannot pers. Each additional paper, s ust have its own certificate of n	be used for any other
STEVEN F. WEI						
100 ABBOTT PAI					Certificate of Mailing or Trans hat this Fee(s) Transmittal is al Service with sufficient posta	
DEPT. 377/AP6A				United States Post envelope addresse	al Service with sufficient posta d to the Box Issue Fee address	ge for first class mail in an above, or being facsimile
ABBOTT PARK,	IL 60064-6008			transmitted to the	USPTO, on the date indicated b	pelow.
	•					(Depositor's name)
	,					(Signature) (Date)
						(Date)
APPLICATION NO.	FILING DATE	FIRS	T NAMED INVEN	FOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/874,493	06/05/2001		Ronny van't Oeve		6811.US.O1	6161
SIMULTANEOUS ANALY				ELL DIFFERENTI	ATION ON A CELL-BY-CE	LL BASIS, AND
APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLI	CATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1300		\$300	\$1600	08/07/2003
EXAMI	NER	ART UNIT	CLASS-SUBCI	ASS		
HESS, DA	NIEL A	2876	356-03900	0		
CFR 1.363). Change of correspond Address form PTO/SB/1		Correspondence	2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2			
PTO/SB/47; Rev 03-02 Number is required.	on (or "Fee Address" Indica or more recent) attached. Us	tion form se of a Customer		t attorneys or agent he will be printed.	s. If no name	
3. ASSIGNEE NAME AND PLEASE NOTE: Unless a been previously submitted (A) NAME OF ASSIGNE	n assignee is identified belo to the USPTO or is being so	ow, no assignee data wi ubmitted under separate	ll appear on the p cover. Completion	atent. Inclusion of a	assignee data is only appropria T a substitute for filing an assig OUNTRY)	te when an assignment has gnment.
Please check the appropriate	e assignee category or category	ories (will not be printed	l on the patent)	individual C	corporation or other private g	roup entity government
4a. The following fee(s) are	enclosed:	4b. Pay	ment of Fee(s):			
☐ Issue Fee				of the fee(s) is enclor. I. Form PTO-2038 i		
□ Publication Fee		_ *	•		is attached. / charge the required fee(s), or o	credit any overnayment to
Commissioner for Patents is		Deposit	t Account Numbe	r	(enclose an extra copy of this ly paid issue fee to the applicat	form).
(Authorized Signature)		(Date)				
other than the applicant;	d Publication Fee (if require a registered attorney or age cords of the United States P	gent; or the assignee or	r other party in			
This collection of informational obtain or retain a benefit application. Confidentiality estimated to take 12 minus completed application for case. Any comments on suggestions for reducing (Patent and Trademark 22313-1450. DO NOT ST	tion is required by 37 CFF by the public which is to by is governed by 35 U.S.C. tes to complete, including a m to the USPTO. Time we the amount of time you his burden, should be sent Office, U.S. Department END FEES OR COMPLIFOR Patents, Alexandria, Vin	R 1.311. The information file (and by the USPTC 122 and 37 CFR 1.14. The gathering, preparing, and ill vary depending upor require to complete the Chief Information of Commerce, Alexa ETED FORMS TO THE	n is required to to process) an his collection is the individual	·	· .	
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09/874,493		06/05/2001 Ronny van't Oever		6811.US.O1	6161	
23492	7590	05/07/2003	·	EXAMINI	BR	
STEVEN F. WEINSTOCK				HESS, DANIEL A		
ABBOTT LABO				ART UNIT	PAPER NUMBER	
DEPT. 377/AP6A ABBOTT PARK, IL 60064-6008			2876			
				DATE MAII ED: 05/07/2003		

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The patent term adjustment to date is 2 days. If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the term adjustment will be 2 days.

If a continued prosecution application (CPA) was filed in the above-identified application, the filing date that determines patent term adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) system. (http://pair.uspto.gov)

Any questions regarding the patent term extension or adjustment determination should be directed to the Office of Patent Legal Administration at (703)305-1383.



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09/874,493	09/874,493 06/05/2001		Ronny van't Oever	6811.US.O1	6161	
23492	7590	05/07/2003		EXAMINER		
STEVEN F.	WEINSTO	CK	HESS, DANIEL A			
ABBOTT LAI			ART UNIT	PAPER NUMBER		
100 ABBOTT	PARK ROA	AD		ARTONII	PAPER NUMBER	
DEPT. 377/AF	P6A		2876			
ABBOTT PAR	RK, IL 6006	4-6008				
INITED STA	TEC		DATE MAILED: 05/07/2003			

Notice of Fee Increase on January 1, 2003

If a reply to a "Notice of Allowance and Fee(s) Due" is filed in the Office on or after January 1, 2003, then the amount due will be higher than that set forth in the "Notice of Allowance and Fee(s) Due" since there will be an increase in fees effective on January 1, 2003. See Revision of Patent and Trademark Fees for Fiscal Year 2003: Final Rule, 67 Fed. Reg. 70847, 70849 (November 27, 2002).

The current fee schedule is accessible from: http://www.uspto.gov/main/howtofees.htm.

If the issue fee paid is the amount shown on the "Notice of Allowance and Fee(s) Due," but not the correct amount in view of the fee increase, a "Notice to Pay Balance of Issue Fee" will be mailed to applicant. In order to avoid processing delays associated with mailing of a "Notice to Pay Balance of Issue Fee," if the response to the Notice of Allowance and Fee(s) due form is to be filed on or after January 1, 2003 (or mailed with a certificate of mailing on or after January 1, 2003), the issue fee paid should be the fee that is required at the time the fee is paid. If the issue fee was previously paid, and the response to the "Notice of Allowance and Fee(s) Due" includes a request to apply a previously-paid issue fee to the issue fee now due, then the difference between the issue fee amount at the time the response is filed and the previously paid issue fee should be paid. See Manual of Patent Examining Procedure, Section 1308.01 (Eighth Edition, August 2001).

Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

			<i>!</i>				
•	Application No.	Applicant(s)					
Aladiaa af Allawahilita	09/874,493	OEVER ET AL.					
Notice of Allowability	Examiner	Art Unit					
	Daniel A Hess	2876					
	Daniel A Less	2010					
The MAILING DATE of this communication apper All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RI of the Office or upon petition by the applicant. See 37 CFR 1.313	(OR REMAINS) CLOSED or other appropriate commendates. This application is	in this application. If not include nunication will be mailed in due of	ed course. THIS				
1. This communication is responsive to <u>response of 3/31/200</u>)3						
2. The allowed claim(s) is/are <u>1-20</u> .	<u>-</u> .						
3. The drawings filed on are accepted by the Examine	r						
4. Acknowledgment is made of a claim for foreign priority und		or (f)					
a) ☐ All b) ☐ Some* c) ☐ None of the:	10, 00 0,0.0. 3 , , (0,0)	J. (1).					
 Certified copies of the priority documents have 	been received.						
Certified copies of the priority documents have	been received in Applicat	ion No					
3. Copies of the certified copies of the priority do	cuments have been receive	ed in this national stage applicat	ion from the				
International Bureau (PCT Rule 17.2(a)).							
* Certified copies not received:							
5. Acknowledgment is made of a claim for domestic priority u	nder 35 U.S.C. § 119(e) (to	a provisional application).					
(a) The translation of the foreign language provisional a	pplication has been receive	ed.					
6. Acknowledgment is made of a claim for domestic priority u	nder 35 U.S.C. §§ 120 and	/or 121.					
Applicant has THREE MONTHS FROM THE "MAILING DATE" of below. Failure to timely comply will result in ABANDONMENT of							
	7. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.						
 8. ☐ CORRECTED DRAWINGS must be submitted. (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached 1) ☐ hereto or 2) ☐ to Paper No 							
(b) including changes required by the proposed drawing correction filed, which has been approved by the Examiner.							
(c) ☐ including changes required by the attached Examiner	(c) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No						
Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet.							
9. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.							
Attachment(s)							
1 Notice of References Cited (PTO-892)	2□ Notice	of Informal Patent Application (F	PTO-152\				
3 Notice of Preferences Cited (FTO-692) 3 Notice of Draftperson's Patent Drawing Review (PTO-948)		ew Summary (PTO-413), Paper I					
5☐ Information Disclosure Statements (PTO-1449), Paper No		ner's Amendment/Comment	·				
7☐ Examiner's Comment Regarding Requirement for Deposit	8⊠ Examir	ner's Statement of Reasons for A	√llowance				
of Biological Material	9☐ Other	•					

Art Unit: 2876

DETAILED ACTION

1. Receipt is acknowledged of response dated 3/31/2003, which has been placed in the file of record, and to which this action is a reply.

REASONS FOR ALLOWANCE

- 2. Claims 1-21 are allowed. The following is a statement of the examiner's reasons for allowance.
- 3. Re claims 1-12 and 21: The nearest available prior art of record, Tycko (US 5,194,909), shows (column 7, line 66; column 4, lines 65-70) the sphering of red blood samples using sphering reagent. The solution is (column 8, lines 8-15) a neutrally buffered saline solution (7.4 pH). Individual cells are 'entrained' (column 5, line 4). There is a 'stream' (column 15, line 51) of liquid containing the cells. Light of a particular color is shone on the cells (column 5, line 9; column 9, line 41). Tycko further shows that scattering measurements are taken at two particular angles (figures 4 and 5). These are 'forward scattering' measurements (column 5, lines 10-12). Tycko does show the use of plots to correlate the three variables of volume (V), HC and a scatter signal in figures 4 and 5, although he only shows this in two dimensions. However, in doing so, Tycko illustrates the principle of using gridded lines in a third variable to include 3 variables in 2 dimensions. Tycko also shows that a given measurement of scattering at a certain angle forms a single 'equation' for the variables of volume V and hemoglobin concentration HC (see figures 4 and 5). In figures 4 and 5, Tycko effectively shows two such equations.

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Tycko notably fails to teach or suggest "projecting a three-dimensional coordinate of light scatter signals from each cell onto a three-dimensional surface containing grid lines of V and HC."

Nowhere else does the prior art of record teach or suggest the 3-dimensional analytical techniques claimed by the applicant for using a variety of scatter signals to obtain measurements of hemoglobin concentration and blood volume.

4. Re claims 13-20: The applicant's arguments regarding claim 13 in the action of 3/31/2003 were persuasive. The examiner agrees that certain elements taught in the prior art were lacking in Tycko as modified by Altendorf as applied to claim 13 of the previous action.

In particular, Tycko doesn't employ the same type of multi-angle light scattering as in the claimed invention. Further, as the applicant points out, large angle scattered light photo detectors are employed in Altendorf, and these are explicitly for Altendorf's white blood cell analysis. They are not designed to be dual-use.

The examiner did not find indication elsewhere in the prior art of record of teachings of the full limitations of claim 13.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel A Hess whose telephone number is (703) 305-3841. The examiner can normally be reached on 8:00 AM - 5:00 PM M-F.

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- 6. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Lee can be reached on (703) 305-3503. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7722 for regular communications and (703) 308-7722 for After Final communications.
- 7. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0956.

DH

May 2, 2003

Daniel A Hess Examiner Art Unit 2876

KARL D. FRECH PRIMARY EXAMINER